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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,042	04/27/2001	Filippo Belardelli	B-4161 618742-8	1462
466	7590	04/10/2006	EXAMINER	
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EWOLDT, GERALD R	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 04/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/845,042

Applicant(s)

BELARDELLI ET AL.

Examiner

G. R. Ewoldt, Ph.D.

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— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 54,55,57,58,61-63,66,67 and 69-83 is/are pending in the application.
- 4a) Of the above claim(s) 82 and 83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 54,55,57,58,61-63,66,67 and 69-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

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#### DETAILED ACTION

1. Applicant's amendment and remarks filed 2/21/06 are acknowledged.
2. Newly submitted Claims 82 and 83 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims recite the treatment of mice with the cells of the claimed method of producing DCs.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 82 and 83 are withdrawn from consideration as being directed to a non-elected species of the claimed method. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 54, 55, 57, 58, 61-63, 66, 67, 69-71, and newly added Claims 72-81 are pending and under examination.

3. In view of the instant amendments, the previous rejections under the second paragraph of 35 U.S.C 112 have been withdrawn. Additionally, the previous rejections under the first paragraph of 35 U.S.C 112 for inadequate written description for the introduction of new matter into the claims has also been withdrawn. Finally, the previous rejection 35 U.S.C. 102(b) has also been withdrawn. Note that Paquette et al. does not teach deriving DCs in 3 or fewer days.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 54, 55, 57, 58, 61-63, 66, 67, 69-71, and newly added Claims 72-81 stand/are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. Elements critical or essential to the practice of the invention,

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but not included in the claims are not enabled by the disclosure, for the reasons of record.

As set forth previously, the specification discloses that only cultures employing 1000 IU/ml IFN resulted in functional DCs. Accordingly, the use of 1000 IU/ml IFN in the claimed method would be considered essential to the instant invention. Likewise, all disclosed cultures employed 500 IU/ml GM-CSF ... Applicant's own disclosure provides additional basis in the teaching that 100 U of IFN was ineffective in the claimed method ... Thus, the use of 500 IU/ml GM-CSF in the claimed method would also be considered essential to the instant invention.

Note that post-filing data has established that concentrations of IFN as low 500 IU/ml would function in the claimed method.

Applicant's arguments, filed 2/21/06, have been fully considered but they are not persuasive. Applicant argues that "The specification expressly teaches that type I IFN may be present in preferred ranges of 100-10,000 IU/ml, 400-10,000 IU/ml, 500-2,000 IU/ml, particularly 1,000 IU/ml. The present specification also plainly states that the GM-CSF may be preferably used at a concentration in a range of 250-1,000 IU/ml".

While the specification may assert said "preferred ranges", neither it, nor the prior, nor post-filing art, enable said ranges.

Applicant cites MPEP 2164.02 and argues that all the facts in evidence must be considered in making a valid rejection.

MPEP 2164.02 is noted, and the facts in the case have been considered. The facts show that there is no evidence of record that IFN and GM-CSF concentrations below 500 IU/ml would function in the method of the instant claims. Indeed, the only facts of record regarding low cytokine concentrations are that an IFN concentration of 100 IU/ml does not function in the claimed method. Given the unexpected nature of the claimed method, it remains the Examiner's position that a showing of enablement commensurate in scope with the claimed method, i.e., that low concentrations of IFN and GM-CSF would function to derive DCs from monocytes in no more than 3 days, is required.

Applicant cites 2 post-filing references, Santodonato et al. and Lapenta et al. in support of the claimed method.

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First note that the references are not of record, however, they would seem to support the Examiner's position and not Applicant's. Santodonato et al. teaches the use of GM-CSF at 500 IU/ml and IFN at 1000 IU/ml. Lapenta et al. teaches the use of GM-CSF at 500 IU/ml and IFN at 10,000 IU/ml. As the rejection is for the use of cytokine concentrations below 500 IU/ml each of GM-CSF and IFN, these references fail to support Applicant's position.

6. The following are new grounds for rejection necessitated by Applicant's amendment.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 57, 58, and 61 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the claims depend from canceled claims.

9. Claims 54, 55, 57, 58, 61-63, 66, 67, 69-71, and newly added Claims 72-81 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) A process ... in the absence of IL-4 ... for a maximum of 3 days ... (Claims 54, 63).

B) A process ... in the absence of added IL-4 ... for a maximum of 3 days ... collecting cells within 3 days (Claim 69).

C) ... IFN is present in a concentration range of 500-10,000 IU/ml (Claims 57 and 63, **note:** Claim 57 was improperly amended, i.e., the change was not shown on the Claim).

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D) ... GM-CSF at a concentration range of 500-1000 IU/ml (Claims 61 and 63).

F) The characteristics recited in Claims 72-81 as applied to DCs ... for a maximum of 3 days (Claim 72) or within 3 days (Claims 72-76).

G) TM-CSF (Claim 75).

H) CM-CSF (Claims 79-81).

Regarding A-D), no support has been provided and none has been found. Applicant argues in response to a previous rejection that the term "in the absence of IL-4" or "in the absence of added IL-4" is implicitly supported by the specification. It remains the Examiner's position that "implicit" support is insufficient.

Regarding F), the characteristics refer to dendritic cells or mature dendritic cells, but not the partially mature dendritic cells disclosed at page 5 of the specification, i.e., the cells provided within 3 days. Further note that the experiments cited in support of the new claims comprised a duration of 3 days and not within 3 days or a maximum of 3 days.

Regarding G) and H), the terms are not found in the specification.

10. No claim is allowed.


11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

13. **Please Note:** Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see [www.uspto.gov/ebc/newusers.html](http://www.uspto.gov/ebc/newusers.html). Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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